

**K201588 CRYOCARE TOUCH System and Accessories,
Endocare 1.7mm Round Ice PerCryo Cryoprobe, Short, Round
Ice**Aug 11, 2020
60 days to decisionK201588 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k201588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jun 12, 2020
Decision date	Aug 11, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems, Inc.
Location	Palo Alto, CA, US
Contact	Peter J. Coronado
Website	http://www.varian.com
510(k) history	170 submissions · 170 cleared · 1997-2026

Varian Medical Systems, Inc. is an American radiation oncology company based in Palo Alto, California. The company develops medical devices and software for cancer treatment and radiotherapy. Varian Medical Systems, Inc. has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's regulatory portfolio is dominated by Radiology devices, representing 96% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. The company specializes in linear accelerators (LINACs), ra...
